

**REMARKS**

Claims 16-20 and 24-35 are cancelled without prejudice . Applicant has added claims 36-42 to better define the anhydrous aspect of the invention consistent with the following remarks.

35 USC §112, First Paragraph, Written Description

Because the newly recited claims specify a dry admixture, Applicant notes that the specification describes a dried bacterial compositions comprising dried viable bacteria, dried non-living yeast and a protein concentrate, primarily available commercially in dried form, page 6, line 21, and page 8, lines 1-12. Further support for the “dried” nature of the composition when admixed may be found on page 10, line 16 (“when mixed in a dry state”), page 8 lines 19-24, and page 18 lines 9-11.

The previous rejection regarding the “dry weight” formulation is obviated in the newly presented claims by reciting the proportions of the compositions as a percent of the “total mass” of the composition as per the express language of the specification, see e.g. p. 10, lines 10-14, lines 21-25. Applicant submits that a person of ordinary skill in the art of food preparation would have no difficulty in understanding the “total mass” language used in the application and claims. The rejection regarding the language directed to the length of viability of the bacteria in the composition is rendered moot by the deletion of that limitation from the newly presented claims.

Applicant notes the double patenting rejection over co-pending application 08/879,220. At an appropriate time, a terminal disclaimer will be filed if the claims as allowed in the present application remain coextensive with application 08/879,220.

Art-based Rejections Under § 102/103(a).

The new claims have been re-formulated to insure that the cited references do not, when taken alone or in any combination, disclose each and every limitation of the claimed compositions and that no motivation exists in the record to combine the cited references in a manner to render the new claims anticipated, nor to create a *prima facie* case of obviousness.

To be certain that the content of the prior art references cited in the record is completely understood, Applicant has obtained a new translation of the Levy reference (EP 0 430 736 A1) which is enclosed herewith. The Levy reference merely discloses combination of *Bifido bifidum* (Bifidus) bacteria and yeast, wherein the yeast component can be lactic-acid yeast or Brewer's yeast. No other components apart from the Bifidus bacterial component and the yeast component are disclosed. Moreover, the relative percent concentration of the yeast component in the Levy compositions is no less than 85% yeast. Although the relative concentrations of lactic-acid yeast and Brewer's yeast vary in different embodiments, the concentration of yeast is never less than 85%. Thus, the compositions of Levy do not meet the concentrations element recited for the yeast component in the claimed invention. Furthermore, *Bifido bifidum* bacteria is the only bacterial species disclosed. Neither *Lactobacillus* nor any of the other strains disclosed by the present invention are taught by Levy and Levy discloses nothing about the additional protein concentrate element recited in the present composition.

To anticipate a claim, a reference must contain each and every element set forth in the claim, see MPEP §2131. Furthermore, in order to anticipate a range limitation in the claim, the reference must show an example within that range or a range overlapping, touching or within the claimed range. See MPEP §2131.03. Although a second reference may be used to explain the meaning of a

term in a reference offered for anticipation purposes, or to show that an inherent characteristic exists in the reference, the secondary reference may not be used to expand the terms of the reference offered for anticipation. See MPEP 2131.01.

It is asserted that the disclosed compositions in the Levy reference anticipate the claimed dried bacterial compositions because A) the viable bacterial *bifidus* is present within the claimed range, B) the Brewer's yeast component and lactic acid bacteria component of the composition are a "concentrated sources of protein," and thus equivalent to the claimed protein concentrate component. Applicant submits that this analysis is flawed because the claims cannot be so construed as to read out express range limitation for the yeast component of the invention. Because the Levy reference clearly does not contain the claimed percentage of yeast, and because the characterization of yeast and bacteria as protein concentrates due to the assertion that they are "an art recognized source of concentrated protein" is not supported by the cited references and impermissibly reads out the protein concentrate element of the claimed compositions, Levy cannot anticipate. Thus none of the compositions described in Levy meet disclose the species of bacteria, the percent concentration of the non-living yeast component, nor the protein concentrate. Therefore, Levy cannot anticipate the current claims.

#### §103(a) Rejection

A *prima facie* case of obviousness cannot be established, and the claims are not obvious under § 103 over the cited references, because none of the cited references teach a dry admixture of the components of the claimed composition.

As noted in the previous response, two well-established principles of the law of obviousness under 35 U.S.C. § 103 dictate that first, the cited prior art references must be considered "as a

whole” and must suggest the desirability and thus the obviousness of making the combination.

Second, the combination cannot be reconstructed from the references with the “benefit of impermissible hindsight.” See MPEP § 2141, Basic Considerations Which Apply to Obviousness Rejections. Although the remaining references of record disclose additional components in isolation, some of which overlap with the components of the present invention, each of the references is incomplete and suffers from a fatal defect which precludes its use in a rejection of the newly-presented claims under § 102 or 103(a). As is noted from the following, a specific flaw in the teaching of the secondary references is the failure to disclose [a dry admixture of the components of the claimed compositions.] For example, El-Megeed et al. (USP 4,897,350) discloses a composition for use in the baking of Baladi bread. In the background section, El-Megeed et al. disclose:

The formula for Baladi bread dough consists of high extraction (82-88%) flour, water [,] salt, and 12-17% starter (fermented dough). } prior to

In each case, El-Megeed teach the fermentation of the dough using water as part of the formulation in which the yeast is mixed. For example, at column 9, line 50, El-Megeed et al. disclose:

In another embodiment, there is provided a method for creating a starter material useful for enhancing the protein quality of wheat and bread. To create the starter in one aspect, a basic formula of soft wheat flour of 82% extraction, 100 parts; table salt 1.2 parts; water, 70 parts (v/w); and freeze-dried bacterial cells were used. The water proportion was varied within certain limits (the 65% v/w often used). (emphasis added).

It is clear from the disclosure of El-Megeed et al. that the fermentation step, which is a prerequisite to the utility of the compositions disclosed in El-Megeed, require water. At column 10, lines 44-45, El-Megeed state:

The amount of water needed depended on the water absorption of the flour, which was variable.

Referring to the examples, Example 3 (column 14, lines 30-34) clearly demonstrates that water is used in the composition of El-Megeed et al. See also (column 14, lines 54-55, column 17, line 23, column 18, lines 26 and 65, and Table 9).

Similarly, Jolly (USP 4,107,334) uses water or a water-based liquid in every example of the modified protein described therein. For example, Example 1 states: “a portion (32.7g) of the wet heat-denatured whey protein solids (10.1g dry) was dispersed in 100ml water.” Example 2 states: “a portion (10g) of the heat denatured whey protein solids was dispersed in 90ml water.” See also Examples 4-7 (column 7 at line 15). Example 8 states: “*S. cerevisiae* yeast cells (800g wet, 172g dry) were dispersed in a 1000ml water ...” and “The resulting slurry was centrifuged and the centrifuged cake was washed with water to yield 392g wet heat-denatured yeast protein solids (72g dry).” Example 9 states: “A sample of 200g of dry heat-denatured *S. cerevisiae* yeast protein solids was slurried in 1000ml effanol, filtered and washed with water.” Example 10 states: “The wet heat-denatured soy protein solids was slurried in 300ml water.” Example 11 states: “A 50g sample of dry soy whey solids was dissolved in 150ml water.” A major component in Example 12 is water (see column 9, line 20). Similarly, Example 13 contains all of vinegar, vegetable oil, and water (see column 9, lines 47, 53 and 57). Example 14 discloses boiling water, and states: “The boiling water was added to the pre-blended dry ingredients and the mixture was whipped...” See column 10, lines 29 and 30. Finally, each of Examples 15 through 28 disclose water (See column 10, line 66; column 11, lines 34, 38-45; column 12, lines 15, 48, 51; column 13, lines 17, 51; column 14, lines 25, 29-33, 65; column 15, lines 27, 59; column 16, lines 19, 50, 51-56; column 17, line 39; and column 18, line 4.

Therefore, Jolly clearly does not disclose a dry admixture of any compositions and to obtain the anhydrous composition of the present claims, one must fundamentally depart from the teachings of Jolly and El-Megeed.

The Prescott reference describes brewer's and baker's yeast in terms of production and protein content. Prescott also describes the use of brewer's yeast in animal feed and baker's yeast in dietary supplements. According to Prescott, brewer's yeast comprises about 40 % protein, and baker's yeast comprises about 50-55% protein. Prescott does not describe yeast as a particularly concentrated source of protein.

The Friend reference discusses the beneficial properties of *Lactobacillus* cultures, in general, including their nutritional and therapeutic benefits. As with El-Megeed et al. and Jolly, the Friend reference discloses only the administration of *Lactobacillus* in wet cultured dairy products, specifically yogurt and milk. The Friend reference does not mention a dried admixture containing yeast and bacteria, such as *Lactobacillus*, and does not suggest combining *Lactobacillus* and whey protein concentrate.

Considering the references in combination, none of the references can cure the defect in Levy such that a protein concentrate may be added to the disclosed formulation. The claimed compositions comprise a protein concentrate. Applicants submit that the plain meaning of this term for one of ordinary skill in the art is a relatively purified form of protein, rather than a "source" of protein. Thus, the third claimed component does not encompass powdered milk, blood meal, sawdust containing moderate amounts of lignin, or other putative "sources" of protein. The Jolly and Prescott references are offered in combination with the Levy reference to remedy the lack of a protein concentrate in the disclosed formulation. As mentioned above, the claimed protein concentrate is distinct from a mere "source" of protein. Thus, the assertion that the Prescott and

Jolly references teach that yeast contains protein, and is thus equivalent to the “protein” in the compositions utilized in the claimed methods, does nothing to remedy the lack of a protein concentrate in the Levy reference when compared to the claims compositions.

Furthermore, neither the Friend nor the Jolly reference suggests the addition of a protein concentrate to a bacteria and yeast composition. The Friend reference provides no impetus to add a protein concentrate to the compositions described in Levy, or to modify them in any other way. Friend does not describe nor suggest any methods of prolonging the viability of *Lactobacillus* cultures in dried bacterial compositions, nor does Friend even describe any such compositions. The Friend reference describes the use of bacterial cultures in milk and yogurt, neither of which is a protein concentrate. As described above, the general teachings of Friend that *Lactobacillus* cultures are “desirable” additions to nutritious product is not a sufficient motivating suggestion for one of ordinary skill in the art to make the specific combination of the claimed proportions of bacteria, yeast, and protein concentrate.

Therefore, under the proper legal standard, one of ordinary skill in the art, possessing the teachings of Levy, Jolly, Prescott, El-Megeed et al. and Friend would not discard the teachings that include water in the formulations, nor substitute *Lactobacillus* for the *Bifidus bifidum* of Levy, nor add the protein concentrate as claimed without reference to the present disclosure to provide the dry admixture of these components as the invention. To do so would require modifying the plain teaching of the references that disclose a wet composition, would require substituting the species of bacterium in Levy for those recited in the new claims, and would require adding a component to Levy that is nowhere stated therein. Moreover, the desirability of such a combination is not disclosed in any of the references. Such a reformulation would violate the rule explained in In re Gordon, 733 F.2d 900 (Fed. Cir. 1984) wherein the Federal Circuit held that a prior art reference

may not be modified in a way that would render the prior art invention unsatisfactory for its intended purpose (See MPEP § 2143.01). Clearly, the removal of water from a teaching of a formulation that is water-based would render the art unsatisfactory for the intended purpose. Further, with respect to the total mass percentages, a prior art reference describing a composition of matter with similar parameters will only render a claimed similar composition obvious by "optimization" of the parameters if the parameter was art recognized as result-effective. In Re Antonie 195 USPQ 6 (CCPA 1977) (See MPEP § 2144.05, II. B.). None of the parameters recited in the claims is shown in the art to be successfully altered to achieve the result here.

Applicant respectfully requests reconsideration and allowance of the newly presented claims.

Respectfully submitted,

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